AMENDMENTS TO THE CLAIMS

1-12. (Cancelled).

13. (Currently amended) A method of treating a disease or disorder in a body area [[of]] where bone regeneration is required to ameliorate said disease or disorder, in an immunocompetent subject ~~where bone regeneration is required~~, said method comprising administering ~~locally~~ directly to a skeletal muscle of said body area a therapeutically effective amount of a nucleic acid molecule comprising an adeno-associated viral vector and a promoter which is operably linked to~~: (a) a nucleotide sequence of SEQ ID NO:1; or (b)~~ a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2,

wherein said disease or disorder is selected from the group consisting of bone fracture non-union, segmental bone defects, spinal fusion, periodontal disease, degenerative disc disease, and growth plate injury.

14. (Original) The method of claim 13, wherein said promoter is a promoter of bone morphogenetic protein.

15. (Previously Presented) The method of claim 13, wherein said promoter is a CAG promoter comprising a chicken beta-actin promoter and a human cytomegalovirus enhancer.

16-22. (Cancelled).

23. (Currently amended) A method of treating a disease or disorder in a body area [[of]] where bone regeneration is required to ameliorate said disease or disorder, in an immunocompetent subject ~~where bone regeneration is required~~, said method comprising administering ~~locally~~ directly to a skeletal muscle of said body area

a therapeutically effective amount of a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter, and a second nucleic acid molecule comprising an adenoviral vector and a second promoter, wherein the first and second promoters are each operably linked to ~~either: (a) a nucleotide sequence of SEQ ID NO:1; or (b)~~ a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2,

wherein said disease or disorder is selected from the group consisting of bone fracture non-union, segmental bone defects, spinal fusion, periodontal disease, degenerative disc disease, and growth plate injury.

24. (Original) The method of claim 23, wherein said first promoter and/or said second promoter is a promoter of bone morphogenetic protein.

25. (Previously Presented) The method of claim 23, wherein said first promoter and/or said second promoter is a CAG promoter comprising a chicken beta-actin promoter and a human cytomegalovirus enhancer.

26. (Currently amended) The method of claim 23, wherein said first and second nucleic acid molecules are administered concurrently ~~to a skeletal muscle of said body area~~.

27-28. (Cancelled).

29. (Currently amended) A method of treating a diseased or injured body area of an immunocompetent subject, said method comprising administering ~~locally~~ directly to a skeletal muscle of said body area a therapeutically effective amount of a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter which is operably linked to a first nucleotide sequence encoding a therapeutic gene product; and a second nucleic acid molecule comprising an adenoviral vector and

a second promoter which is operably linked to a second nucleotide sequence encoding a therapeutic gene product,

wherein said diseased or injured body area is inflicted with cancer.

30. (Previously Presented) The method of claim 23 or 29, wherein the adenoviral vector is administered at an amount that is non-toxic and non-immunogenic in the subject.

31. (Previously Presented) The method of claim 29, wherein the said first and/or second promoter is a CAG promoter comprising a chicken beta-actin promoter and a human cytomegalovirus enhancer.

32. (Previously Presented) The method of claim 13, 23 or 29, wherein the subject is a human.

33-34. (Cancelled).

35. (Currently amended) A method for expressing a bone morphogenetic protein (BMP) for new bone formation in a body area of a subject, comprising administering ~~locally~~ directly to a skeletal muscle of said body area an effective amount of a nucleic acid molecule comprising an adeno-associated viral vector (AAV) and a promoter which is operably linked to a nucleotide sequence encoding the BMP.

36. (Previously Presented) The method of claim 35, wherein said BMP is BMP-2.

37. (Currently amended) The method of claim 35, wherein the nucleotide sequence encoding the BMP has: ~~(a) the nucleotide sequence of SEQ ID~~

~~NO:1; or (b)~~ a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2.

38. (Previously Presented) The method of claim 35, wherein said promoter is a promoter of the BMP.

39. (Previously Presented) The method of any one of claims 35-37, wherein said promoter is a CAG promoter comprising a chicken beta-actin promoter and a human cytomegalovirus enhancer.

40. (Cancelled).

41. (Currently amended) A method for expressing a bone morphogenetic protein (BMP) for new bone formation in a body area of a subject, comprising administering ~~locally~~ directly to a skeletal muscle of said body area an effective amount of a first nucleic acid molecule comprising an adeno-associated viral vector and a first promoter, and a second nucleic acid molecule comprising an adenoviral vector and a second promoter, wherein the first and second promoters are each operably linked to a nucleotide sequence encoding the BMP.

42. (Previously Presented) The method of claim 41, wherein said BMP is BMP-2.

43. (Currently amended) The method of claim 41, wherein the nucleotide sequence encoding the BMP has~~: (a) the nucleotide sequence of SEQ ID NO:1; or (b)~~ a nucleotide sequence that encodes the amino acid sequence of SEQ ID NO:2.

44. (Previously Presented) The method of claim 41, wherein the amount of the adenoviral vector is a dosage that is non-toxic and non-immunogenic in the subject.

45. (Previously Presented) The method of claim 41, wherein said first promoter and/or said second promoter is a promoter of bone morphogenetic protein.

46. (Previously Presented) The method of claim 41, wherein said first promoter and/or said second promoter is a CAG promoter comprising a chicken beta-actin promoter and a human cytomegalovirus enhancer.

47. (Currently amended) The method of claim 41, wherein said first and second nucleic acid molecules are administered concurrently ~~to a skeletal muscle of said body area~~.